CLAIMS

1. A pharmaceutical aerosol formulation to be administered by pressurized metered dose inhalers which comprises an active ingredient selected from salmeterol or a stereoisomer, physiologically acceptable salt and solvate thereof, in solution in a propellant system, said propellant system consisting of a liquefied HFA propellant, a co-solvent and 0 to 5% w/w water, characterised in that the amount of the cosolvent is no more than 35% w/w on the total weight of the formulation.

2. A pharmaceutical formulation according to claim 1, wherein the co-solvent is selected from the group of lower alkyl (C1-C4) alcohols, polyols, polyalkylene glycols, (poly)alkoxy derivatives and their combinations.

3. A pharmaceutical formulation according to claim 2 wherein the cosolvent is ethanol.

4. A pharmaceutical formulation according to claim 3 wherein the amount of water is from 0.5% to 5% w/w and ethanol is no more than 25% w/w.

5. A pharmaceutical formulation according to claims 1-4 wherein the amount of water is up to 3% w/w.

6. A pharmaceutical formulation according to claims 1-5 wherein the fraction of particles equal to or less than 1.1 μm delivered on actuation of the inhaler, the superfine fraction, is higher than or equal to 30% as defined by the content of the stages S6-AF of an Andersen Cascade Impactor, relative to the content of the stages S6-AF, according to the method referred to in the description on page 16 lines 16 to 24.

7. A pharmaceutical formulation according to claims 1-6 wherein the superfine fraction is higher than 40%.

8. A pharmaceutical formulation according to claims 1-7 wherein the active ingredient is salmeterol xinafoate.

9. A pharmaceutical formulation according to claim 8 wherein the active ingredient is in a concentration of between 0.005 and 0.15% w/v.

10. A pharmaceutical formulation according to any preceding claim wherein the pH is comprised between 2.5 and 5.5.

11. A pharmaceutical formulation according to claim 10 wherein the pH is adjusted by adding a mineral acid.

12. A pharmaceutical formulation according to any preceding claim, wherein the propellant includes one or more hydrofluoroalkanes [HFAs] selected from the group comprising HFA 134a and HFA 227.

13. A pharmaceutical formulation according to claims 1-12 comprising 0.04% w/v salmeterol, 15% w/w ethanol and 2% w/w water.

14. A pharmaceutical formulation according to any preceding claim filled in a canister having part or all of its internal metallic surfaces made of standard aluminium, stainless steel, anodised aluminium or lined with an inert organic coating.

15. A pharmaceutical formulation according to any preceding claim comprising a further active ingredient selected from the class of steroids such as beclomethasone dipropionate, fluticasone propionate, ciclesonide, budesonide and its 22R-epimer or anticholinergic atropine-like derivatives such as ipratropium bromide, oxitropium bromide, tiotropium bromide.

16. A method of preparing the pharmaceutical formulations of claims 1-15, the method comprising:

(a) preparing of a solution of one or more active ingredients in one or more co-solvents;

(b) optionally adding a proper amount of water and adjusting the pH of the solution;

(c) filling of the device with said solution;

(d) crimping with valves and gassing.

(e) adding a propellant containing a hydrofluoroalkane (HFA).

17. A method according to claim 16 wherein the device in provided with a valve actuator whose orifice diameter is 0.22 mm.

18. A pharmaceutical formulation according to any one of claims 1 to 17 for the treatment of respiratory diseases.

19. A pharmaceutical formulation according to claim 18 in which the respiratory disease is asthma or Chronic obstructive pulmonary disease (COPD).

20. A pharmaceutical formulation according to claim 19 in which the respiratory disease is due to obstruction of the peripheral airways as a result of inflammation or mucus hypersecretion.

21. A pharmaceutical formulation according to claim 18 wherein the respiratory disease is pulmonary edema or surfactant-deficiency related disorder such as acute lung injury (ALI) or acute respiratory distress syndrome (ARDS).